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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,662	01/23/2002	Daniel J. Benedict		9818

26357 7590 06/20/2005

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EXAMINER

LANKFORD JR, LEON B

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/056,662

Applicant(s)

BENEDICT, DANIEL J.

Examiner

Leon Lankford

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34, 36-46 and 61-83 is/are pending in the application.
- 4a) Of the above claim(s) 76-79 and 83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34, 36-46, 61-75 and 80-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

*Claim Rejections - 35 USC § 112*

Newly submitted claims 76-79 & 83 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the apparatus could be used to perform other biochemical reactions that require tissue digestion as the monitoring of essential growth parameters, e.g. primary hepatocyte culture formation.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 76-79 & 83 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant has argued that the prior art does not recognize the parameters to be monitored as result effective variables, however this is not the case and seems in contrast to applicant's filed declarations and the specification (along with the cited prior art). Applicant's specification clearly sets forth that the variables monitored in the instant method (as well as means for their control) are known in the art and that the sensors, microprocessors and software were also known. Applicant appears to have set forth that their invention is the monitoring of all the identified variables and automating the process as a whole. The prior art does not teach this, however in an art that recognizes the value of monitoring and controlling variables of a cellular process

and automating said monitoring and controlling, it would have been obvious to monitor and control all of these known variables in the processing of islets as a matter of optimizing the production of the islets.

Applicant's arguments have been considered however a showing to overcome a prima facie case of obviousness must be clear and convincing( In re Lohr et al. 137 USPQ 548) as well as commensurate in scope with the claimed subject matter ( In re Lindner 173 USPQ 356; In re Hyson, 172 USPQ 399 and In re Boesch et al., 205 USPQ 215 (CCPA 1980).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-30 & 36-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to set forth the subject matter which applicant(s) regard as their invention.

Applicant repeated discusses in their specification and declarations that the invention lies in the monitoring and controlling of all the disclosed variables not just a select few. At the very least the claimed invention must contain the use, monitoring and control of a digestive enzyme.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1651

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-30 & 36-60 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling.

The use, monitoring and controlling of a digestive enzyme is critical or essential to the practice of the invention, but not included in the claim(s). Thus the claims excluding these critical elements is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-34, 36-46 & 61-75 & 80-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mullen (5919703), Langley(5273904) and/or Scharp (5377790) in view of Kearney(5424209) and Shuler et al(5612188).

Mullen, Langley and Scharp all teach methods of isolating islets from a pancreas including all of the culture/digestion steps claimed by applicant. The references do not teach using controllers to control all the experimental parameters of the process, however at the time the invention was made, it would have been obvious to control all the experimental parameters of an islet isolating process because the three references clearly teach that these parameters are result effective variables and would be routinely optimized by one of ordinary skill in the art at the time the invention was made. It would further have been obvious to use automated/computerized controllers to control the experimental parameters because the state of the art clearly uses such means to do so. For example, Kearney and Shuler teach automated cell culture/handling processes in which controllers are programmed to sense and optimize the growth/maintenance of the culture. Applicant's claims are still broad and vague, essentially claiming the automated control of a process wherein the parameters that need to be controlled are all recognized and the means for controlling them are all old and well known in the art.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

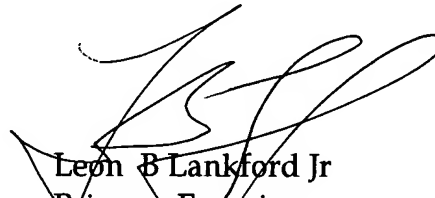
§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leon B Lankford Jr  
Primary Examiner  
Art Unit 1651

LBL